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EXAMINER				
ELEY, JESSICA L				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,568

Applicant(s)

KIMCHY ET AL.

Examiner

JESSICA L. ELEY

Art Unit

2884

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 33-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE/CI)
Paper No(s)/Mail Date 8/25/2006; 10/19/2005; 05/05/2008; 08/15/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-32 in the reply filed on 17 April 2008 is acknowledged.

Claims 33-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 17 April 2008.

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Objections

Claim 27 is objected to because of the following informalities: the phrase "by a second modality" seems to appear more times than necessary in the second paragraph of claim 27. The

passage in question states “imaging *by a second modality*, a second device, for obtaining a second, structural image, *by a second modality*...” Examiner feels the clarity of the claim would be improved by removing this second reference to the limitation “by a second modality,” and the limitation “a second device,” since “a first device,” does not appear with “a first modality.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation “said motor” in line 1 of claim 25. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-10, 12-14, 18, 22, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig et al US 5,672,877 (henceforth referred to as Liebig)**.

Regarding **claim 1**, Liebig teaches an imaging apparatus, comprising:

A first device, for obtaining a first image, by a first modality, selected from the group consisting of SPECT, PET, CT, x-rays (column 10 lines 31-34), an extracorporeal gamma scan (column 3 lines 57-62), an intracorporeal gamma scan, and a combination thereof, wherein said first image is registered to a system of coordinates (column 5 lines 20-23);

A second device, for obtaining a second, structural image, by a second modality, selected from the group consisting of an MRI (column 12 lines 13-16); and

A computerized system, which comprises a registrator for co-registering said second, structural image to said system of coordinates (column 12 lines 13-16 and column 11 lines 34-41, FIG. 8), and an attenuation-instruction generator configured to compute a set of attenuation instructions for said first image, based on said second, structural image (column 4 lines 15-34).

It is noted that Liebig does not limit the second modality to any specific kind of MRI, namely an MRI operative by an internal magnetic field, an extracorporeal MRI operative by an external magnetic field, an intracorporeal MRI operative by an external magnetic field, instead using simply the term “MRI” as a suggestion of possible non-SPECT modalities. Since Liebig did not limit the second modality to any specific kind of MRI it is understood that all forms of MRI are encompassed.

Liebig does not expressly teach the first modality being is: an extracorporeal beta scan, an intracorporeal beta scan, an intravascular gamma scan, or an intravascular beta scan; nor does he expressly teach the second modality comprising: a three-dimensional ultrasound, an extracorporeal ultrasound, an intracorporeal ultrasound, an intravascular ultrasound, and a combination thereof. Liebig does suggest that in the field of medical imaging ultrasound imaging should be considered along with CT and fluoroscopy (column 1 lines 13-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the technique and apparatus of the coregistered medical imaging system as taught by Liebig to these additional medical imaging techniques as a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

Regarding **claim 2**, Liebig teaches the imaging apparatus of claim 1, wherein said computerized system is further configured to compute, based on said a set of attenuation instructions an attenuation-corrected image of said first image (column 4 lines 15-34).

Regarding **claim 3**, Liebig teaches the imaging apparatus of claim 2, wherein said computerized system is further configured to display a superposition of said attenuation-corrected first image and said second, structural image (column 11 lines 34-41).

Regarding **claims 5 and 6**, Liebig teaches the imaging apparatus of claim 1, wherein said registrator for coregistering said second, structural image to said system of coordinates relies on that said first and second devices share a single position-registration device (column 10 lines 54-58) and have substantially equal position-registration devices (column 10 lines 58-63), for co-registering said second, structural image to said system of coordinates.

Regarding **claim 7**, Liebig teaches the imaging apparatus of claim 1, wherein said registrator for coregistering said second, structural image to said system of coordinates relies on fiduciary marks (markers, column 2 lines 12-32) visible both on said first image and on said second, structural image, for co-registering said second, structural image to said system of coordinates.

Regarding **claim 8**, Liebig teaches an imaging apparatus, comprising:

A first detector, for obtaining a first image, by a modality, selected from the group consisting of a gamma scan (column 4 lines 29-34), wherein said first image is registered to a system of coordinates (column 5 lines 20-23);

A second detector, for obtaining a second, structural image, by a modality, selected from the group consisting of MRI (column 12 lines 14-19); and

A computerized system, which comprises a registrator for co-registering said second, structural image to said system of coordinates (column 10 lines 54-63), and an attenuation-instruction generator configured to compute a set of attenuation instructions for said first image, based on said second, structural image (column 4 lines 15-34).

Liebig does not expressly teach the group for the first modality including a beta scan and the second group consisting of ultrasound. Liebig does suggest that in the field of medical imaging ultrasound imaging should be considered along with CT and fluoroscopy (column 1 lines 13-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the technique and apparatus of the coregistered medical imaging system as taught by Liebig to these additional medical imaging techniques as a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

Regarding **claim 9**, Liebig teaches the imaging apparatus of claim 8, wherein said computerized system is further configured to compute, based on said a set of attenuation instructions an attenuation-corrected image of said first image (column 4 lines 23-28).

Regarding **claim 10**, Liebig teaches the imaging apparatus of claim 9, wherein said computerized system is further configured to display **105** a superposition of said attenuation-corrected first image and said second, structural image (block **806** in FIG. 8).

Regarding **claims 12 and 13**, Liebig teaches the imaging apparatus of claim 8, wherein said registrator for coregistering said second, structural image to said system of coordinates relies on that said first and second devices share a single position-registration device (column 10 lines 54-58) and have substantially equal position-registration devices (column 10 lines 58-63), for co-registering said second, structural image to said system of coordinates.

Regarding **claim 14**, Liebig teaches the imaging apparatus of claim 8, wherein said registrator for coregistering said second, structural image to said system of coordinates relies on fiduciary marks (markers, column 2 lines 12-32) visible both on said first image and on said second, structural image, for co-registering said second, structural image to said system of coordinates.

Regarding **claims 18 and 22**, Liebig teaches the imaging apparatus of claim 8, but does not expressly teach the imaging apparatus designed to be inserted through a trucar valve or designed as a handheld, extracorporeal probe. However, Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques such as a coronal views, etc. (column 12 lines 19-21). It would have been obvious to one of ordinary skill in the art at the time the invention was made to design the imaging apparatus to be inserted through a trucar valve or designed as a handheld extracorporeal probe, as a person of ordinary skill in the art has good reason to pursue the options within his or her technical grasp.

Regarding **claim 27**, Liebig teaches an imaging method, comprising:

Imaging by a first modality, selected from the group consisting of SPECT, PET, CT, x-rays (column 10 lines 31-34), an extracorporeal gamma scan (column 3 lines 57-62), an intracorporeal gamma scan, and a combination thereof, wherein said first image is registered to a system of coordinates (column 5 lines 20-23);

Imaging by a second modality using a second device for obtaining a second structural image, selected from the group consisting of an MRI (column 12 lines 13-16);

Co-registering said second, structural image to said system of coordinates (column 12 lines 13-16 and column 11 lines 34-41, FIG. 8); and

Computing a set of attenuation instructions for said first image, based on said second, structural image (column 4 lines 15-34).

It is noted that Liebig does not limit the second modality to any specific kind of MRI, namely an MRI operative by an internal magnetic field, an extracorporeal MRI operative by an external magnetic field, an intracorporeal MRI operative by an external magnetic field, instead using simply the term "MRI" as a suggestion of possible non-SECT modalities. Since Liebig did not limit

the second modality to any specific kind of MRI it is understood that all forms of MRI are encompassed.

Liebig does not expressly teach the first modality being is: an extracorporeal beta scan, an intracorporeal beta scan, an intravascular gamma scan, or an intravascular beta scan; nor does he expressly teach the second modality comprising: a three-dimensional ultrasound, an extracorporeal ultrasound, an intracorporeal ultrasound, an intravascular ultrasound, and a combination thereof. Liebig does suggest that in the field of medical imaging ultrasound imaging should be considered along with CT and fluoroscopy (column 1 lines 13-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the technique and apparatus of the coregistered medical imaging system as taught by Liebig to these additional medical imaging techniques as a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

Regarding **claim 28**, Liebig teaches the imaging method of claim 27, further comprising computing an attenuation-corrected first image based on said a set of attenuation instructions (column 4 lines 15-34).

Regarding **claims 29 and 30**, Liebig teaches the imaging method of claim 27, wherein said computerized system is further configured to display **806** a superposition of said attenuation-corrected first image and said second, structural image (column 11 lines 34-41).

Claims 4, 11, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 3, 8 and 30 respectfully above, and further in view of **Front et al. US 6,368,331 B2** (henceforth referred to as **Front**).

Regarding **claims 4, 11, and 31**, Liebig teaches the imaging apparatus of claims 3 and 8 and the imaging method of claim 30, as discussed above, but does not teach the apparatus further including an instrument, registered to said system of coordinates and visible on at least one of said first image and said second, structural image and wherein said computerized system is further configured to guide said instrument in-vivo, based on said superposition. Front teaches a medical imager that combines the image from a PET scanner and a CT or MRI while simultaneously guiding therapeutic instrument **520** using guide device **506** (FIG. 7). It would be obvious to one of ordinary skill in the art at the time the invention was made to use the therapeutic instrument and guide device taught by Front with the teachings of the coregistered medical image taught by Liebig, since Front teaches that there is a need for accessing a correct target region inside the patient's body with a diagnostic or therapeutic instrument (column 2 lines 46-49).

Claims 15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 3 and 30 respectfully above, and further in view of **Fry et al. US 4,951,653** (henceforth referred to as **Fry**).

Regarding **claims 15 and 32**, Liebig teaches the imaging apparatus of claim 8 and the imaging method of claim 30, but does not specifically detail the embodiment further comprising an ultrasound transducer operative of focused ablation. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Fry teaches an ultrasound brain lesioning system that uses transducer **29** for focused ablation (column 8 lines 14-19). The apparatus taught by Fry uses ultrasound, CT or MRI scans in order to obtain the feature data of a target, in this case a brain tumor, to accurately control the mechanical drive of the transducer (column 4 lines 18-21). It would

have been obvious to one of ordinary skill in the art at the time the invention was made to use the ultrasound transducer with the coordinate medical imaging taught by Liebig, as Liebig provides coregistered images from a variety of sources such as SPECT, CT and MRI, thus generating a more accurate scan data that Fry acknowledges is desirable with the ultrasound transducer (column 2 lines 2-10).

Claims 16, 17, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 8 above, and further in view of **Benaron et al. US 6,246,901 B1** (henceforth referred to as **Benaron**).

Regarding **claims 16 and 17**, the disclosure of Liebig teaches all of the limitations of the imaging apparatus of claim 8, as discussed above. Liebig does not directly disclose the scenario of the imaging system is designed as a rectum probe, or as an endoscope probe; however such adaptations are common in the art. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Benaron teaches a system for detecting, localizing and targeting a medical instrument toward a target tissue by means of a rectal probe (column 18 lines 51-56) or endoscopes (column 19 lines 6-10). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to design the imaging apparatus taught by Liebig as a rectal probe or as an endoscope probe as a person of ordinary skill has good reason to pursue the known options within his or her technical grasp, and Benaron teaches that an object of the device is to enhance localization by combining both structural and biochemical images simultaneously (column 5 lines 33-46), such as is accomplished by Liebig.

Regarding **claim 23**, Liebig teaches an imaging apparatus, comprising:

A first detector, for obtaining a first image, by a modality, selected from the group consisting of a gamma scan (column 4 lines 29-34), wherein said first image is registered to a system of coordinates (column 5 lines 20-23);

A second detector, for obtaining a second, structural image, by a modality, selected from the group consisting of MRI (column 12 lines 14-19); and

A computerized system, which comprises a registrator for co-registering said second, structural image to said system of coordinates (column 10 lines 54-63), and an attenuation-instruction generator configured to compute a set of attenuation instructions for said first image, based on said second, structural image (column 4 lines 15-34).

Liebig does not expressly teach the group for the first modality including a beta scan and the second group consisting of ultrasound. Liebig does suggest that in the field of medical imaging ultrasound imaging should be considered along with CT and fluoroscopy (column 1 lines 13-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the technique and apparatus of the coregistered medical imaging system as taught by Liebig to these additional medical imaging techniques as a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

Liebig does not teach the imaging apparatus comprising an intracorporeal portion. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Benaron teaches a system for detecting, localizing and targeting a medical instrument toward a target tissue by means of a rectal probe (column 18 lines 51-56). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an intracorporeal portion in the design of the imaging apparatus taught by Liebig, since Benaron teaches that the closer the imager can get to the portion

being imaged the as a rectal probe or as an endoscope probe as a person of ordinary skill has good reason to pursue the known options within his or her technical grasp, and Benaron teaches that an object of the device is to enhance localization by combining both structural and biochemical images simultaneously (column 5 lines 33-46) and teaches that it is an advantage to monitor more than one modality at a time (column 7 lines 54-58) such as is accomplished by Liebig.

Regarding **claim 24**, the disclosures of Liebig and Benaron teach the rectal probe of claim 23, further comprising movable collimators, operative as vents (Benaron column 10 lines 16-19).

Regarding **claim 25**, the disclosures of Liebig and Benaron teach the rectal probe of claim 23, wherein said motor

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 3 above, and further in view of **Funda et al. US 5,572,999 (henceforth referred to as Funda)**.

Regarding **claim 19**, Liebig teaches the imaging apparatus of claim 8, but does not specifically detail the apparatus designed to be mounted on a resectoscope. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Funda teaches using the data from preoperative medical images such as CT or MRI in order to pre-program a specialized robotic device for stepping a resectoscope through a sequence (column 1 lines 51-64). It would have been obvious to one of ordinary skill in the art at the time the invention was made to mount the apparatus taught by Liebig on a resectoscope since the images provided by Liebig are multi-modal and coregistered providing a

more defined image for the control of the robotics of the resectoscope, as taught by Funda, and thus provide more accurate incisions.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig** as applied to claim 8 above, and further in view of **Sieben et al. US 5,243,988 (henceforth referred to as Sieben)**.

Regarding **claims 20 and 21**, the disclosure of Liebig teaches all of the limitations of the imaging apparatus of claim 8, as discussed above. Liebig does not directly disclose the scenario of the imaging system is designed to be inserted in a catheter, or designed for intravascular imaging, however in the art of medical imaging these modifications are common. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Sieben for example teaches a medical imaging system designed to be inserted in a catheter or designed for intravascular imaging. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the imaging apparatus taught by Liebig in order to be inserted in a catheter and intravascular imaging as taught by Sieben since a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Liebig and Benaron** as applied to claim 23 above, and further in view of **Fry et al. US 4,951,653 (henceforth referred to as Fry)**.

Regarding **claim 26**, the disclosures of Liebig and Benaron teach the rectal probe of claim 23, but does not specifically detail the embodiment further comprising an ultrasound transducer operative of focused ablation. Liebig does acknowledge that the technique of coregistered images may be applied to any types of views obtaining using medical imaging techniques (column 12 lines 19-21). Fry teaches an ultrasound brain lesioning system that uses transducer **29** for focused ablation (column 8 lines 14-19). The apparatus taught by Fry uses ultrasound, CT or MRI scans in order to obtain the feature data of a target, in this case a brain tumor, to accurately control the mechanical drive of the transducer (column 4 lines 18-21). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ultrasound transducer with the coordinate medical imaging taught by Liebig, as Liebig provides coregistered images from a variety of sources such as SPECT, CT and MRI, thus generating a more accurate scan data that Fry acknowledges is desirable with the ultrasound transducer (column 2 lines 2-10).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JESSICA L. ELEY whose telephone number is (571)272-9793. The examiner can normally be reached on Monday - Thursday 8:00-6:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L. E./
Examiner, Art Unit 2884
/David P. Porta/
Supervisory Patent Examiner, Art Unit 2884